## 510(K) SUMMARY

K093998

This 510(k) summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92(c).

| | |
|---|---|
| Applicant | OrthAlign, Inc.<br>6 Cromwell<br>Suite 102<br>Irvine, CA 92618<br>Tel: (949) 715-2424<br>Fax: (866) 204-9844 |
| Official Correspondent | Amy Walters<br>AWE, Inc.<br>338 Vista Madera<br>Newport Beach, CA 92660<br>amy@orth-align.com<br>Tel: (949) 923-9400<br>Fax: (866) 204-9844 |
| Trade Name | KneeAlign™ System with Reference Sensor |
| Common Name | Stereotaxic Instrument |
| Device Classification | Class II, 21 CFR §882.4560 |
| Product Codes | OLO: Orthopedic Stereotaxic Instrument |
| Predicate devices | KneeAlign System (K091411)<br>BrainLAB Knee Essential (K073615)<br>TOTAL KNEE SURGETICS Navigation System (K060282) |

MAR 22 2010

Substantially Equivalent To:

The KneeAlign™ System with Reference Sensor is substantially equivalent to the previously cleared KneeAlign System (K091411), BrainLAB Knee Essential(K073615), and TOTAL KNEE SURGETICS Navigation System (K060282).

Description of the Device Subject to Premarket Notification:

The KneeAlign System with Reference Sensor is an innovative non-invasive computer assisted surgical navigation system for use in knee arthroplasty procedures. The KneeAlign System is configured to detect, measure, and display angular measurement changes in a triaxial format.

The current standard of care for knee arthroplasty procedures has the physician estimating these changes either by visual observation and tactile feedback or with assistance of computer assisted surgery devices. The KneeAlign System with Reference Sensor utilizes a palm-sized computer module and reference sensor to generate positional information in orthopedic procedures providing a sequence of steps for registration of anatomical landmarks, calculation of mechanical axes, and positioning of instruments relative to the mechanical axes. In knee arthroplasty procedures, the device assists the surgeon in establishing the mechanical axis of the tibia, determining the varus/valgus angle and the posterior slope angle of the cutting block relative to tibia.
The KneeAlign System with Reference Sensor comprises a single use computer module and reusable instrumentation.

Indications for Use:

The KneeAlign System with Reference Sensor has the same indications for use as the previously cleared KneeAlign System (K091411).

The KneeAlign System with Reference Sensor is a computer controlled system intended to assist the surgeon in determining reference alignment axes in relation to anatomical structures during stereotactic orthopedic surgical procedures. The KneeAlignSystem with Reference Sensor facilitates the accurate positioning of implants and instrumentation, relative to these alignment axes.
Example orthopedic surgical procedures include but are not limited to:

- Total Knee Arthroplasty/tibial resection

Technical Characteristics:

The KneeAlign™ System with Reference Sensor comprises a single use computer module, a reusable reference sensor, and reusable tibial jig. The device utilizes algorithms to convert sensor outputs into spatial coordinates, providing graphical representation of instruments and anatomy on the user display screen.

Performance Data:

Simulated use testing confirms that the KneeAlign System with Reference Sensor can be used according to its intended use. The KneeAlign System with Reference Sensor has been verified and validated according to OrthAlign's procedures for product design and development. The safety and performance of the KneeAlign System with Reference Sensor has been validated to insure it meets its intended use, including:

- Bench Testing: System accuracy testing, performance testing, laser testing
- Software Validation
- Cleaning and Sterilization Validation
- Biocompatibility Assessment
- Electrical Safety and Electromagnetic Compatibility Testing
  - Safety Requirements for Medical Electrical Equipment (IEC

60601-1)
- Electromagnetic Compatibility (EMC) Requirements (IEC 60601-1-2), and
- Simulated Use/Cadaver Testing

This testing regime demonstrates that the subject device is substantially equivalent to the legally marketed predicate devices, for its intended use.

The information provided by OrthAlign in this 510(k) application was found to be substantially equivalent to predicate devices such as the KneeAlign System (K091411), BrainLAB Knee Essential (K073615) and the TOTAL KNEE SURGETICS Navigation System (K060282).

Basis for Determination of Substantial Equivalence:

A technological comparison and bench, and cadaver testing demonstrate the substantial equivalence of the KneeAlign System with Reference Sensor to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

MAR 22 2010

OrthAlign, Inc.
% AWE, Inc.
Ms. Amy Walters
338 Vista Madera
Newport Beach, California 92660

Re: K093998
Trade/Device Name: KneeAlign™ System with Reference Sensor
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: OLO
Dated: March 01, 2010
Received: March 03, 2010

Dear Ms. Walters:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## SECTION 2. INDICATIONS FOR USE STATEMENT

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K093998

Device Name: KneeAlign™ System with Reference Sensor

Indications for Use:

The KneeAlign™ System with Reference Sensor is a computer controlled system intended to assist the surgeon in determining reference alignment axes in relation to anatomical structures during stereotactic orthopedic surgical procedures. The KneeAlign™ System with Reference Sensor facilitates the accurate positioning of implants and instrumentation, relative to these alignment axes.
Example orthopedic surgical procedures include but are not limited to:

- Total Knee Arthroplasty

Prescription Use __x____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K093998